K130876

APR 2 6 2013

06 **510(K) SUMMARY**

Submitter Information

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Date Prepared:	March 27, 2013

Device Name

Device Trade Name: CG+ Arrow PICC powered by Arrow VPS Stylet
Common Name, Catheter: Peripherally Inserted Central Catheter (PICC)

Classification Name, Catheter: Percutaneous, implanted, long-term intravascular catheter per 21 CFR: 880.5970

Predicate Devices

- K123759: CG+ Arrow PICC powered by Arrow VPS Stylet

Device Description

The CG+ Arrow PICC powered by Arrow VPS Stylet has the following characteristics:

- 6 Fr, 3-Lumen, 40-55 cm pressure injectable, antimicrobial and antithrombogenic catheter preloaded with VPS Stylet

The CG+ Arrow PICC is pre-loaded with the Arrow VPS Stylet and will be provided in sterile kit configurations.

The Arrow CG+ PICC is a short-term or long-term, single use catheter designed to provide access to the central venous system. It consists of a non-tapered, radiopaque polyurethane extruded catheter body with a softer, contoured Blue Flex Tip. The catheter can be used for the injection of contrast media. The maximum recommended infusion rate is 6 mL/sec. The external catheter body and the internal fluid path of the device are treated with Chlorhexidine based coating technology. Studies have shown the technology to possess both antimicrobial and antithrombogenic properties.

The Arrow VPS Stylet is a polyimide tube containing a Doppler sensor on a coax cable and an intravascular electrocardiogram (ivECG) signal sensing stainless steel wire. The Doppler sensor and the exposed portion of the ivECG are located at the distal end of the stylet and are used to detect and transmit physiological information to the VPS Console for analysis. The proximal end contains a connector to the VPS Console or to an extension cable that in turn connects to the VPS Console. The stylet was designed to be able to be inserted and removed from any catheter with a luminal diameter of at least 0.021 inch.

The number of lumens has increased from 2 to 3 and as a result the subject device's French size has increased from 5.5 to 6 French. In order to identify the third lumen, an additional colorant and ink were used. Additionally, the internal lumen configuration of the predicate (K123759) has changed from a "Round-Crescent" to a "Round-Split-Crescent". The "Round-Split-Crescent" internal lumen design modification resulted in an increased flowrate in the distal lumen from a maximum of 5 ml/sec to 6 ml/sec. (The proximal and medial lumen are not pressure injectable on the subject device.) The increased surface area on the subject device's 6 French 3-L catheter design resulted in a 3.8 mg increase in the maximum allowable chlorhexidine content as compared to the predicate device (the content per surface area remains unchanged).

Intended Use

A PICC permits venous access to the central circulation through a peripheral vein.

The intended use of the VPS Stylet and Console (VPS System) is to quickly and accurately guide market available central catheters to the desired location which is the lower third of the SVC or at the cavo-atrial junction.

Technological Characteristics and Substantial Equivalence

The subject CG+ Arrow PICC powered by Arrow VPS Stylet is substantially equivalent to the predicate CG+ Arrow PICC powered by Arrow VPS Stylet (K123759) in terms of indications for use, manufacturing process, conditions and aids, functional performance, safety, efficacy, fundamental scientific technology and materials of construction. There is no change to the Arrow VPS Stylet from the predicate device. The design of the predicate CG+ Arrow PICC has been modified to create the subject device. The number of lumens has increased from 2 to 3 and as a result the subject device's French size has increased from 5.5 to 6 French. In order to identify the third lumen, an additional colorant and ink were used. Additionally, the internal lumen configuration of the predicate (K123759) has changed from a "Round-Crescent" to a "Round-Split-Crescent". The "Round-Split-Crescent" internal lumen design modification resulted in an increased flowrate in the distal lumen from a maximum of 5 ml/sec to 6 ml/sec. (The proximal and medial lumen are not pressure injectable on the subject device.) The increased surface area on the subject device's 6 French 3-L catheter design resulted in a 3.8 mg increase in the maximum allowable chlorhexidine content as compared to the predicate device (the content per surface area remains unchanged). Biocompatibility (toxicity, etc.) testing on the final finished device verified that the increase in maximum allowable chlorhexidine content of 3.8 mg/catheter did not present any new safety or efficacy concerns. The chlorhexidine's content per

surface area remains the same; therefore, efficacy and analytical release profile of the chlorhexidine were shown to be unaffected. Efficacy testing verified efficacy is unaffected.

The antimicrobial/antithrombogenic chlorhexidine coating's identity, formulation, concentration (content per surface area), manufacturing processes, conditions and aids, method of application to the device and mechanism by which the agent is released from the device is the same as the predicate CG+ Arrow PICC powered by Arrow VPS (K123759).

No changes were made to the VPS Stylet.

Nonclinical Testing

The following testing was performed on the 6 French CG+ Arrow PICC powered by Arrow VPS Stylet:

Chlorhexidine coating testing: chlorhexidine content testing, chlorhexidine coating efficacy, chlorhexidine release rate (elution), mechanical hemolysis, solvent residual and chemical degradation.

Catheter performance testing: tensile, catheter body kink, flow rate, static burst pressure, air and liquid leakage, flex cycling, catheter whip, catheter tip compression stiffness, luer hub testing, collapse resistance and central venous pressure monitoring.

Combined device performance testing: stylet tensile, simulated use insertion/removal test and force to remove stylet from catheter. After devices completed the simulated use insertion/removal test, the following tests were done to verify there was no damage to the catheter: catheter air and liquid leakage. Stylet electrical testing was also done post simulated use insertion/removal testing to verify stylet function.

Conclusions

The predicate and the subject devices have the same indications for use, intended use, materials, chlorhexidine formulation, concentration (content per surface area), method of application and mechanism of release and are manufactured using the same processes, conditions and aids. The results of the risk assessment and resultant testing performed have demonstrated that the proposed design and specification changes do not raise new issues of safety or effectiveness and therefore the subject device is considered substantially equivalent to the cited predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 26, 2013

Ms. Elizabeth Duncan
Senior Regulatory Affairs Specialist
Arrow International, Incorporated
2400 Bernville Road
READING PA 19605-9607

Re: K130876
Trade/Device Name: CG+ Arrow PICC Powered by Arrow VPS Stylet
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: March 27, 2013
Received: March 29, 2013

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130876

Device Name: **CG+ Arrow PICC powered by Arrow VPS Stylet**

Indications for Use:

The Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media and allows for central venous pressure monitoring. The maximum pressure of pressure injection equipment used with the pressure injectable PICC catheter may not exceed 300 psi.

Chlorag+ard Technology treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization and thrombus accumulation on catheter surfaces. Antimicrobial and antithrombogenic effectiveness were evaluated using *in vitro* and *in vivo* test methods and no correlation between these test methods and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections or vein thrombosis.

The VPS Stylet and Console are indicated for guidance and tip positioning for central venous catheters. The Stylet provides stiffness for use in placement of the catheter, intravascular capability for ECG detection and recording and intravascular ultrasound for catheter guiding and positioning. The VPS Stylet, when used with the VPS Console, provides real-time catheter tip location information by using the patient's physiological (cardiac electrical activity and blood flow) information. When the VPS System guidance indicator shows a Blue Bullseye, the catheter tip is in the desired location.

The VPS System is indicated for use as an alternative method to fluoroscopy or chest x-ray for central venous catheter tip placement confirmation in adult patients when a steady Blue Bullseye is obtained. NOTE: If a steady Blue Bullseye is not obtained, standard hospital practice should be followed to confirm catheter tip location.

Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia and pacemaker-driven rhythm, and in central venous catheterization procedures performed through femoral or saphenous vein access which change the presentation of the P-wave. In such patients, who are easily identifiable prior to central venous catheter insertion, the use of an additional method is required to confirm catheter tip location.

Prescription Use ___ X ___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA

Richard C. Chapman
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(Division Sign-Off)
vision of Anesthesiology, General Hospital
tection Control, Dental Devices

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